DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303) 236-3000 Fax:(303) 236-3100 Industry Information: www.fda.gov/oc/industry	04/20/2015 - 04/27/2015
	FEI NUMBER 3010894019

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Darby C. Brown, President

FIRM NAME	STREET ADDRESS
Brown's Compounding Center, Inc.	13796 Compark Blvd Ste 100
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Englewood, CO 80112-7146	Outsourcing Facility

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

Specifically,
Papaverine HCL ([redacted] (b) (4)) 30 mg/ml stock solution compounded on 1/15/2015; Beyond Use Date of June 13, 2015 was frozen and re-thawed [redacted] times for the production of [redacted] different finished product lots. The formulation worksheet states to refrigerate. There is no assurance of the drug product stability after each reuse. In addition, there are no established procedures for the use and manufacture of sterile stock solutions produced at the firm.

OBSERVATION 2

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established.

Specifically,
There was no post [redacted] (b) (4) conducted on the [redacted] (b) (4) used for the following aqueous and oil/aqueous drug products: testosterone cypionate, hydroxyprogesterone, lipolean, methylcobalamin, fentanyl, hydromorphone, fentanyl/bupivacaine, phenylephrine, norepinephrine, magnesium sulfate and dimethy sulfoxide/dimethyl sulfone (16 lots total).

OBSERVATION 3

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications prior to release.

Specifically,
It was observed on 4/20/2015, during a walk through of your facility, a visual inspection in-progress of Lipolean lot 02242015+186507 not being performed with the contrasting white black background. SOP 3.30.6 titled, "Sterile Product Final Inspection Requirements" does not refer to the use of the contrasting background. In addition, there are no established procedures to qualify technicians to perform a visual inspection on all types of drug products prior to distribution.

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	Erika V. Butler, Investigator Tomika L. Bivens, Investigator	04/27/2015

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OBSERVATION 4

The written stability program for drug products does not include reliable, meaningful, and specific test methods.

Specifically,
Stability analytical methods used for assay analyses of all compounded drugs are not validated (i.e., the accuracy, sensitivity, specificity, and reproducibility of test methods have not been established).

OBSERVATION 5

Written production and process control procedures are not followed in the execution of production and process control functions.

Specifically,

The March 8, 2015 (b) (4) Cleaning log for the Cleanroom Facility, did not have the information completed for the Equipment Cleaner Contact Time and the Floor Cleaner Contact Time.
The (b) (4) Cleaning Log for the Cleanroom for the March 2, 2015 did not have information for the Floor Cleaner Contact Time, Initials of person conducting the clean, initials of person verifying the clean, type of cleaner used and the expiration date of the cleaning supplies used. The only information contained in the cleaning log (b) (4) was the areas cleaned.
On Tues March 3, 2015 the (b) (4) Cleaning Log for the Cleanroom, the information on the Floor Cleaner Contact Time, Initials of Person Verifying, was not present on the form.
On Friday March 6, 2015 the (b) (4) Cleaning Log for the Cleanroom did not have any information entered.
On Wednesday March 11, 2015 the (b) (4) Cleaning Log for the Cleanroom did not have an end time and initials for the Floor Cleaner Contact, also the section of the form Initials of person verifying was not completed.
On Thursday March 12, 2015 the (b) (4) Cleaning Log for the Cleanroom did not contain information regarding the Floor Cleaner Contact Time, nor was the section identified Initials of person Verifying completed.
On Tuesday March 17, 2015 the (b) (4) Cleaning Log for the Cleanroom was not completed.
On Saturday March 28, 2015 the (b) (4) Cleaning Log for the Cleanroom was incomplete in the section identified as Initials of Person Verifying.

OBSERVATION 6

A. The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10). Specifically,

Your firm's labels affixed to the drug products do not contain the date for which the drug was compounded, as required by 503B(a)(10)(A)(iii)(V).

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B. The containers from which the individual units of the drug are removed for dispensing or for administration do not include the following information to facilitate adverse event reporting: www.fda.gov/medwatch and 1-800-FDA-1088 as required by section 503B (a)(10)(B)(ii). For example the following drug products do not contain this information: Vancomycin 150mg/ml, Morphine sulfate/Ketorolac/Tromethamine/Bupivacaine HCL .067mg/.05ml, Gentamicin nasal spray 1mg/ml, and Hydroxyprogesterone caporate 250mg/ml.

EIB 4/27/2015

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